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- (71) Applicant (for all designated States except US): UNIVER-SITY OF UTAH RESEARCH FOUNDATION [US/US]; 615 Arapeen Drive, Suite 110, Salt Lake City, UT 84108 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): KISHORE, Bellamkonda, K. [IN/US]; 1149 Stone Valley Way, Sandý, UT 84094 (US). WESTENFELDER, Christof [US/US]; 702 North Cortez Avenue, Sait Lake City, UT 84103 (US). ISAAC, Jorge [US/US]; 4722 South Millrace Lane, Murray, UT 84107 (US).
- (74) Agents: VILLANUEVA, Lawrence, A. et al.; Needle & Rosenberg, P.C., 999 Peachtree Street, Suite 1000, Atlanta, GA 30309-3915 (US).

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(54) Title: COMPOSITIONS AND METHODS RELATED TO PRODUCTION OF ERYTHROPOIETIN

(57) Abstract: Disclosed are methods and compositions that are related to the production of erythropoiet (57) Abstract: Disclosed are methods and compositions that are related to the production of erythropoietin. The disclosed compositions generally comprise a poly amino acid, such as a poly amino acid comprising one or more glutamic acid residues. The production of erythropoietin by use of the disclosed compositions and methods can take place in vivo, in which the proliferation of a subject's erythropoietin-producing cells leads to an increased level of production of erythropoietin, in vitro, in which increased proliferation of cultured erythropoietin-producing cells leads to an increased production of erythropoietin, ex vivo, in which cells or tissues harvested from a subject produce erythropoietin. The disclosed compositions can be administered to a subject or applied to cells or tissues to stimulate increased production of erythropoietin. The disclosed compositions and methods can be used, for example, to treat anemia, such as anemia associated with diseases and disorders such as chronic renal failure, end stage renal disease, malignancies, HIV infections and AIDS, rheumatoid arthritis, myeloma, and myeloplastic syndrome, and other diseases and disorders.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/11003

A. CLASSIFICATION OF SUBJECT MATTER IPC(7) : A61K 38/00, 47/30, 9/00, 45/00; C12N 5/00, 5/08; C12P 21/06; C08G 69/08 US CL : 514/2, 772.3; 424/280.2, 400; 435/7.21, 68.1, 369, 375, 377; 528/310 According to International Patent Classification (IPC) or to both national classification and IPC B. FIELDS SEARCHED							
Minimum documentation searched (classification system followed by classification symbols) U.S.: 514/2, 772.3; 424/280.2, 400; 435/7.21, 68.1, 369, 375, 377; 528/310							
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched NONE							
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Please See Continuation Sheet							
C. DOCT	JMENTS CONSIDERED TO BE RELEVANT						
Category *	Citation of document, with indication, where ap	propriate, of the relevant passages	Relevant to claim No.				
T	US 6,784,154 B2 (WESTENFELDER) 31 August 20	004 (31.08.2004), entire document.	1-20, 28, 30-39, 41- 51, and 53-102				
x	WO 01/66149 A2 (VALENTIS, INC.) 13 September pp. 33 and 55.	1-15, 19, 20, 28, 30- 39, 41-41, and 53-102					
x	US 6,221,397 B1 (RUSSELL-JONES et al.) 24 April 2001 (24.04.2001), see col. 5, line 1-20, and 28						
. X	TODD, et al. Poly-L-Aspartic Acid Protects Cultured Human Proximal Tubule Cells Against Aminoglycoside-Induced Eletrophysiological Alterations. Toxicology Lett. 1997, Vol. 90, Nos. 2 and 3, pages 217-221, see Figures 1 and 2.						
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	1	See patent family annex.	*				
	r documents are listed in the continuation of Box C.	The later document published after the inte	emational filing date or priority				
	pecial categories of cited documents; t defining the general state of the art which is not considered to be	date and not in conflict with the appli- principle or theory underlying the inv	cation but cited to understand the				
of particular relevance "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone							
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as "Y" considered to involve an inventive step when the combined with one or more other such document			p when the document is th documents, such combination				
"O" document referring to an oral disclosure, use, exhibition or other means being obvious to a person skilled in the art							
"P" documen	priority date claimed						
Date of the actual completion of the international search Date of the international search report Date of the international search report							
02 February	02 February 2005 (02.02.2005)						
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Ale	P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230 Telephone No. (571) 272-1600 U						
Form PCT/ISA/210 (second sheet) (January 2004)							

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/11003

sheet) Observations where certain claims were found unsearchable (Continuation of item 2 of first							
This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following							
reas	ons:	and the second of the second o					
1		Claims Nos.:					
	:	because they relate to subject matter not required to be searched by this Authority, namely:					
2.		Claims Nos.:					
		because they relate to parts of the international application that do not comply with the prescribed requirements to					
		such an extent that no meaningful international search can be carried out, specifically:					
3.	\boxtimes	Claims Nos.: 21-27,29,40 and 52					
		because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule					
	6.4(a).						
Box	No. III	Observations where unity of invention is lacking (Continuation of item 3 of first sheet)					
This	Internat	ional Searching Authority found multiple inventions in this international application, as follows:					
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1		As all required additional search fees were timely paid by the applicant, this international search report covers all					
4.		searchable claims.					
2.		As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite					
		payment of any additional fee.					
3.		As only some of the required additional search fees were timely paid by the applicant, this international search					
	•	report covers only those claims for which fees were paid, specifically claims Nos.:					
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4. No required additional search fees were timely paid by the applicant. Consequently, this international search report							
is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:							
Remark on Protest The additional search fees were accompanied by the applicant's protest.							
No protest accompanied the payment of additional search fees.							
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Form PCT/ISA/210 (continuation of first sheet(2)) (January 2004)

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TERNATIONAL SEARCH REPORT				PCT/US04/11003	•
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Continuation of B. FIELDS SEARCHED Item 3: STN: REGISTRY, CAPLUS, MEDLINE search terms: poly-D,L-glutamic acid, polyD,L-aspartic acid, erythropoietin, cell culture, induce

Form PCT/ISA/210 (extra sheet) (January 2004)